

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 529, and 558

DMB

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Animal Drugs, Feeds, and Related Products; Tylosin Tartrate for Injection, etc.;

Withdrawal of Approval of NADAs

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations by removing those portions that reflect approval of 13 new animal drug applications (NADAs) listed below. In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of the NADAs.

DATES: This rule is effective *[insert date 10 days after date of publication in the Federal Register]*.

FOR FURTHER INFORMATION CONTACT: Pamela K. Esposito, Center for Veterinary Medicine (HFV-210), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-5593.

SUPPLEMENTARY INFORMATION: The following sponsors have requested that FDA withdraw approval of the NADAs listed below because the products are no longer manufactured or marketed:

Sponsor	NADA Number Product (Drug)	21 CFR Cite Affected (Sponsor Drug Labeler Code)
Elanco Animal Health, A Div. of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285.	NADA 12-585 Tylan Injectable (tylosin tartrate)	522.2640b (000986)
.....	NADA 15-207 Hyferdex Injection (iron dextran complex).	522.1183(c) (000986)
.....	NADA 30-330 Tylocine Sulfa Tablets (sulfadiazine, sulfamerazine, sulfamethazine, tylosin).	not applicable
.....	NADA 31-962 Tylan plus Neomycin Eye Powder (neomycin sulfate, tylosin).	524.2640 (000986)
.....	NADA 40-123 Tropic Ointment (cephalonium, flumethasone, iodochlorhydroxyquin, piperocaine hydrochloride, polymyxin B sulfate).	524.321 (000986)
.....	NADA 47-092 Tribodine (ticarbodine)	520.2460a (000986)
.....	NADA 47-353 Ferti-Cept (chorionic gonadotropin)	522.1081(b) (000986)
.....	NADA 92-602 Cephalothin Discs (cephaloridine) ..	529.360 (000986)
.....	NADA 96-678 Tribodine Capsules (ticarbodine)	520.2460b (000986)

Sponsor	NADA Number Product (Drug)	21 CFR Cite Affected (Sponsor Drug Labeler Code)
Bioproducts, Inc., 320 Springside Dr., suite 300, Fairlawn, OH 44333-2435.	NADA 93-518 Tylan® 10 Plus (tylosin phosphate)	558.625(b)(2) (051359)
Young's, Inc., Roaring Spring, PA 16673	NADA 96-162 Hog Grow-R-Mix-4000, Hog Grow-R-Mix-800 (tylosin phosphate).	558.625(b)(13) (035393)
Veterinary Laboratories, Inc., 12340 Santa Fe Dr., Lenexa, KS 66215.	NADA 42-889 Oxytocin Injection (oxytocin)	522.1680(b) (000857)
Weibel Feeds, Inc., Pittsfield, IL 62363	NADA 116-196 Weibel Tylan Premix (tylosin phosphate).	558.625(b)(73) (035098)

Following the withdrawal of approval of these NADAs, Young's, Inc., is no longer the sponsor of any approved applications. Therefore, 21 CFR 510.600(c) is amended to remove the entries for the sponsor.

Elanco Animal Health's NADA 30-330 Tylocine Sulfa Tablets is not codified in 21 CFR part 520. Therefore, an amendment to the regulations for this withdrawal is not required.

As provided below, the animal drug regulations are amended to reflect the withdrawal of approvals.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, 524, and 529

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, 522, 524, 529, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry for “Young’s, Inc.”, and in the table in paragraph (c)(2) by removing the entry “035393”.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.2460 [Removed]

4. Section 520.2460 *Ticarbodine oral dosage forms* is removed.

§ 520.2460a [Removed]

5. Section 520.2460a *Ticarbodine tablets* is removed.

§ 520.2460b [Removed]

6. Section 520.2460b *Ticarbodine capsules* is removed.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

7. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.1081 [Amended]

8. Section 522.1081 *Chorionic gonadotropin for injection; chorionic gonadotropin suspension* is amended by removing and reserving paragraph (b).

§ 522.1183 [Amended]

9. Section 522.1183 *Iron hydrogenated dextran injection* is amended by removing and reserving paragraph (c).

§ 522.1680 [Amended]

10. Section 522.1680 *Oxytocin injection* is amended in paragraph (b) by removing "000857,".

§ 522.2640b [Removed]

11. Section 522.2640b *Tylosin tartrate for injection* is removed.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

12. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 524.321 [Removed]

13. Section 524.321 *Cephalonium, polymyxin B sulfate, flumethasone, iodochlorhydroxyquin, piperocaine hydrochloride topical-otic ointment* is removed.

§ 524.2640 [Removed]

14. Section 524.2640 *Tylosin, neomycin eye powder* is removed.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

15. The authority citation for 21 CFR part 529 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 529.360 [Removed]

16. Section 529.360 *Cephalothin discs* is removed.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

17. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

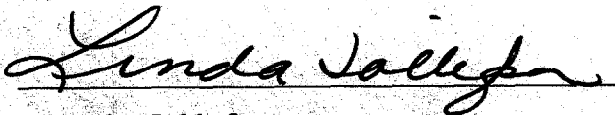


§ 558.625 [Amended]

18. Section 558.625 *Tylosin* is amended by removing and reserving paragraphs (b)(2), (b)(13), and (b)(73).

Dated: 4/23/2001

April 23, 2001.



Linda Tollefson,
Deputy Director, Center for Veterinary Medicine.

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